

EXHIBIT 6

1 IN THE DISTRICT OF THE UNITED STATES OF AMERICA
2 FOR THE SOUTHERN DISTRICT OF ILLINOIS
3 D.W.K., Jr. and parents Mary &
4 Daniel Kaleta,
5 Plaintiff(s),) Case No. **14-847-NJR-SCW**
6 vs.)
7 **ABBOTT LABORATORIES, INC.,**)
8 Defendant(s).)
9

10 **TRIAL DAY 15-a.m.**

13 BE IT REMEMBERED AND CERTIFIED that heretofore on **3/20/2015**,
14 the same being one of the regular judicial days in and for the
15 United States District Court for the Southern District of
16 Illinois, **Honorable Nancy J. Rosenstengel**, United States
17 District Judge, presiding, the following proceedings were
18 recorded by mechanical stenography; transcript produced by
19 computer.

24 **REPORTED BY: Molly N. Clayton, RPR, FCRR**, Official
25 Reporter for United States District Court, SDIL, 750 Missouri
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1 **APPEARANCES:**
2 **John Eddie Williams and John T. Boundas** of Williams
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4 Houston, TX 77017; and,
5 **Phillip Sampson** of Bracewell & Giuliani LLP, 711
6 Louisiana, Suite 2300, Houston, TX 77002; and,
7 **Kenneth T. Fibich** of Fibich Hampton Leebron Briggs &
8 Josephson, LLP, 1150 Bissonnet, Houston, TX 77005; and,
9 **FOR DEFENDANT: Dan H. Ball** of Bryan Cave - St. Louis, 211
10 North Broadway, One Metropolitan Square, Suite 3600, St. Louis,
11 MO 63102; and,
12 **Paul F. Strain and B. Michael MacWilliams** of Venable LLP,
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INDEX OF WITNESS EXAMINATION

DX CX R-DX R-CX

3 No witness testimony.

INDEX OF EXHIBITS

EXHIBIT DESCRIPTION Id'D Rev'd

8 No exhibits identified or received.

MISCELLANEOUS

PAGE

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14 *Jury Instructions, final* 3117
15 *Closing Argument, Plf* 3128

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(Court convened)

(Following proceedings held outside presence of jury:)

3 **COURTROOM DEPUTY:** The matter of *D.W.K. versus Abbott*
4 *Laboratories, Inc.*, Case Number 14-cv-847, is called for day 15
5 of trial.

6 Would the parties please identify themselves for the
7 record?

8 **MR. FIBICH:** Thank you. Good morning, your Honor,
9 Tommy Fibich.

10 **THE COURT:** Good morning.

11 **MR. BOUNDAS:** John Boundas.

12 **MR. WILLIAMS:** John Eddie Williams. Good morning.

13 **THE COURT:** Good morning.

14 **MS. TREVINO:** Good morning. Margot Trevino for
15 plaintiffs.

16 **MR. SAMPSON:** Phillip Sampson, plaintiffs.

17 **THE COURT:** Good morning, everyone.

18 **MR. STRAIN:** Good morning, your Honor. Paul Strain
19 for the defense.

20 **THE COURT:** Good morning, Mr. Strain.

21 **MR. BALL:** Dan Ball for Abbott. Good morning.

22 **THE COURT:** Good morning.

23 **MR. MacWILLIAMS:** Good morning, your Honor. Michael
24 MacWilliams for Abbott.

25 **MR. MARSHALL:** Good morning. Steve Marshall for

Motions

1 labeling or special monitoring programs are needed, this could
2 cast a dark shadow and end up reducing sales."
3 Now ask yourself, number one, does this show you that
4 at least some people within Abbott knew that there was a need
5 for a stronger warning or at least it was a possibility? And
6 this isn't -- you know, Abbott's going to get up and say, well,
7 this was about the black box and we accepted the black box.
8 That's not true at all. I will show you later the testimony.
9 Abbott's own representatives said the black box contained no
10 new information, no new warnings. What Abbott is saying here
11 is if we give a stronger birth defect warning or if we are
12 required to have a special monitoring program -- both of which
13 I think would have been a great idea -- they are going to lose
14 money.

15 Next document.

16 So let's talk about how the studies, how the actual
17 information that Abbott had totally contradicted this marketing
18 strategy.

19 1984. That's when it starts. Article after article
20 after article come out about what's known as Fetal Valproate
21 Syndrome. These are children with multiple birth defects,
22 facial deformations, low IQs, brain damage, spina bifida. Just
23 like Danny. These are multiple malformations in the same child
24 and we don't have one article about it. We have one, two,
25 three, four, five, six, seven. How many do you need to change

Closing Argument, Plf

1 a label? We learned you only need one study to change a label.
2 Remember the Robare study? That got in the label.
3 So here we have Danny, who has Fetal Valproate
4 Syndrome, he's got a cleft lip, skull defect, brain damage,
5 spina bifida, low IQ. He's got Fetal Valproate Syndrome, a
6 syndrome named after this drug.
7 And by 1995 Abbott had all the information they needed
8 to give a warning about that.
9 And what do you think -- and I encourage you at some
10 point that when you are in the jury room look at that warning
11 and read it. You are not going to see anything in there about
12 warning this has a syndrome named after it, this drug can cause
13 multiple malformations in the same child. That's exactly what
14 happened to Danny.
15 But there is more.
16 Next slide.
17 We also showed you in this trial -- and these are
18 studies before 1999 -- there was not a single study in the
19 world that showed that another drug caused spina bifida at a
20 higher rate than valproic acid. Nowhere. And there hasn't
21 been one since. Abbott had 11 studies showing not -- and, you
22 know, they put the 1 to 2 percent in the label but not that
23 their drug was overwhelmingly the most dangerous here. They
24 haven't shown you one study to contradict that.
25 Next slide.

Closing Argument, Plf

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1 Second, study after study after study before 1999
2 showing not 1 to 2 percent. And this isn't spina bifida. This
3 is rate of overall malformations. Do you think this would have
4 something a doctor might want to know, that there is somewhere
5 between ten, you know, seven, 15, 28, 25 percent risk of a baby
6 having a birth defect with this drug? And worse and worse.
7 What we saw -- the evidence showed as the dose of this drug
8 goes up, the risk goes off the charts.

9 Danny was on a high dose. Danny was on 1500
10 milligrams. So here we have -- I can't
11 have. I can't count those, but I would say 12 studies. Not
12 one gets in the label. Nothing in the label about the
13 extremely high rate of birth defects being reported in study
14 after study after study.

15 Next slide.

16 Now, this is something that Dr. Blume showed you. It
17 was an analysis of the studies. And what she did was take all
18 the studies, 1999 and before, and said let's compare them.
19 Let's do some comparisons between the drugs. Valproic acid:
20 17. 3, 3, 3, 2, 1: The competitors. I mean you don't have to
21 be epidemiologist or a neurologist or an FDA expert to see a
22 trend here. Look at the weight of the evidence. This drug was
23 clearly more dangerous. Now, Abbott says, Well, some of these
24 are small studies, some were done in Japan. They've got an
25 excuse for everything.

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1 But 24 studies and nothing? Not one of these gets
2 communicated to a doctor.
3 And, folks, the other thing is, Abbott somehow wants
4 you believe that everything -- that the drug changed.
5 Everything changed after Danny Kaleta was born. We didn't know
6 a thing until after 1999. Nothing changed about this drug. It
7 was valproic acid in 1978, and it is valproic acid today.
8 These studies showed exactly what you would expect because we
9 know today, beyond a shadow of a doubt, it is four times more
10 dangerous than the competing drugs. And that's what the
11 studies showed long before Danny was born.
12 Now, Abbott got up and attacked this chart with
13 Dr. Morrell. But did you see Dr. Morrell bring in another
14 study and say, Hey, you missed one, or, You got that one wrong
15 or, Hey, here is three studies that contradict that?
16 No. She just came in and said, Well, you know, I kind
17 of looked at it all, and I think it is not accurate.
18 We brought you the actual studies, and when you look
19 at them, it is pretty overwhelming.
20 The next slide, please.
21 You know, on the subject of Dr. Morrell saying, Well,
22 some of these are small studies, they were been in Japan, you
23 know, don't worry about it. That's not true at all.
24 I'm sorry about this.
25 THE COURT: Mr. Boundas, I'm sorry. Do you want to

Closing Argument, Plf

1 try to switch out the microphone. I'm sorry. We tried them
2 all this morning, and everything was working fine and...
3 MR. BOUNDAS: Working? I think it's all better.
4 Great. Thanks. Thanks so much. I really appreciate that.
5 Okay. Now we're on track.
6 So they were saying these are small studies, you know,
7 and don't pay any attention to them. That's not true at all:
8 2,111 children exposed to antiepileptic drugs. Valproate was
9 the most dangerous.
10 Next.
11 And I'm not going to show you too many. Bertollini,
12 1997, and this was in Italy: 557 exposed to antiepileptic
13 drugs. Valproic acid is associated with a doubling of the
14 average risk for both major and minor malformations. Two times
15 more dangerous. Not one of these studies was communicated to
16 doctors in the United States, not one.
17 Now, on the subject of Dr. Blume, you know, remember
18 they challenged her credibility, said she was her analysis
19 wasn't accurate. And then what do we find? Abbott, which is a
20 massive pharmaceutical company with their own regulatory
21 department gets sued. They are in litigation. They need help
22 with regulatory issues. Who do they call? Dr. Blume. So I
23 think you consider that when you consider her credibility and
24 what Abbott thought about her before this lawsuit.
25 So let's just say you don't want to take Dr. Morrell's

Closing Argument, Plf

1 word for it. You don't want to take Dr. Blume's word for it.
2 Let's look at what the actual authors of the studies were
3 saying before 1999: 1997, valproic acid should not be used
4 during pregnancy; 1983, not be given during pregnancy; 1985,
5 reduce exposure to the drug among women; 1986, avoid it.
6 Next.
7 1987, avoid it during pregnancy.
8 Only use if there is no alternative.
9 When it cannot be avoided, reduce the daily dose,
10 which, incidentally, was not something Abbott was telling
11 doctors.
12 Replace VPA with another drug when it cannot be
13 avoided.
14 Should not be instituted as the first treatment.
15 Remember Abbott's marketing strategy, first-line?
16 Don't do it.
17 1994: All the other drugs have a risk of fetal
18 effects that is clearly less than valproic acid. These are
19 right out of the articles that Abbott either had or should have
20 had in their files.
21 Associated with a higher prevalence.
22 1995: Replace it with another drug.
23 1996: Its use as far as possible should be avoided
24 during pregnancy.
25 Read that label and tell me if you see a statement

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1 that looks anything like what these articles are saying.
2 This guy Bowden was actually hired -- there was
3 evidence he was hired by Abbott by their marketing department.
4 He wrote an article. It "should not be used during the first
5 trimester of pregnancy." Rule it out and then use
6 contraception.
7 Another article, '98: Should not even be considered
8 for women of childbearing age.
9 1999: Should be avoided. And then we have another
10 one here that talks about how carbamazepine, which is the other
11 drug that Mrs. Kaleta was on back in the '90s should be the
12 agent of choice for women who wish to become pregnant.
13 Those are all quotes from the actual medical
14 literature. So if you want to know who to believe, these were
15 the people doing the studies. These were the researchers out
16 there learning about the drug.
17 Next slide.
18 So what was Abbott doing with these studies? Well, we
19 don't have a whole lot of evidence. I think we have no
20 evidence that they actually read them, analyzed them,
21 summarized them, and I'll show you that evidence as we go. But
22 what we do know is that Abbott's marketing department had some
23 of these studies. Here's one we showed you.
24 It was -- this was -- remember, it was Mr. Murray, who
25 was one of the Abbott representatives, testifying. And he was

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1 talking about the information that they sent to doctors. They
2 were sending out newsletters with articles. And an article
3 comes in that actually says that valproic acid has been
4 recommended for women of childbearing age, but this article
5 calls that into question.
6 Do you think Abbott sent that to doctors? We know
7 they didn't. They crossed that off, and "This abstract is not
8 appropriate."
9 Does that show you what they were thinking? They
10 never sent these articles to doctors. They had all the sales
11 reps, and they were sending all these promotional materials.
12 But when this stuff comes in, it gets crossed out.
13 Next article.
14 And, you know, one thing about this case that you need
15 to consider is that, by withholding this information from
16 doctors, Abbott made the choice for doctors and patients. They
17 were robbed of a meaningful risk benefit choice. Look, if you
18 give people all the information, you let them make their own
19 decision, and they take the risk. But you can only do that if
20 people get the information that they need. And it's not
21 Abbott's decision to say, We are going to tell you which
22 studies you get and which you don't. And we will show you the
23 federal regulations actually require them to do this.
24 So let's talk about the FDA because I know that that's
25 a big theme of Abbott's throughout this trial. This is the

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1 Dr. Morrell admitted it is safer than Depakote. Then you have
2 Depakote, and then you have a whole bunch of other drugs that
3 she could have tried. There were alternatives available.
4 Dr. Taber said that. Dr. McGonagle said that. Even
5 Dr. Morrell admitted that.

6 So at the end of this, Mary Kaleta is taking
7 responsibility for her son 24/7. She's accepted that
8 responsibility. We're asking you to make Abbott accept
9 responsibility for what they did and the role that they played
10 in their drug injuring Daniel.

11 So the last thing I want to cover with you is damages.
12 And you will be asked to fill out the verdict form, and then
13 there are a number of different types of damages that the law
14 allows to be recovered.

15 Some of them are economic damages, and let's go to
16 those. So we put up evidence of Danny's loss of future
17 earnings, whether he is unemployable or even if he manages to
18 get a job. We gave you a range. And then we gave you a range
19 of future and medical expenses if he has home care or if he
20 lives in a facility. And so those were the ranges that you
21 were given. They're in the evidence. And that's just for his
22 medical expenses and future care.

23 But that's money that goes to somebody else. That
24 doesn't go to Danny. That goes to buy catheters. That goes to
25 doctors. That goes to home care places, facilities.

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1 The real damages that Danny suffered are these:

2 Disfigurement, loss of normal life, pain and suffering,
3 emotional distress.

4 I'm not going to ask you how to calculate that. Danny
5 had a lot taken away from him, and, you know, we are not trying
6 to present this as he is a hopeless case. Danny is a great
7 young man, and he is going to make the best of it. He is going
8 to make the absolute best of it. But there is no denying that
9 he got a lot taken away from him: brain damage, spinal
10 damage, damage to his skull, cleft palate, difficulty walking,
11 difficulty using the bathroom, having to catheterize himself,
12 loss of mobility, loss of dignity, wearing diapers.

13 You heard it all. I'm not going to go on. You heard
14 the evidence. Daniel is not going to live the life that he
15 would have lived if he had not been injured. And I suggest to
16 you that this -- what was taken away from him is not
17 calculable, but it is a heck of a lot more than what's going to
18 be paid to buy catheters and pay for his home care and the
19 things that he needs simply because Abbott injured him.

20 There is an important decision to be made by you
21 today. It's a real important decision. And today it's true
22 that you, as a jury, a federal jury, you have the power, not
23 the judge, not me, not the lawyers. You have the power as a
24 federal jury to tell Abbott that they are responsible for the
25 damage they did to this child. And we are asking you at the

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1 end of this case to make Abbott accept responsibility for what
2 they did. And that's all the time I have right now. I'll --
3 Mr. Fibich will address you later.

4 *THE COURT:* Thank you, Mr. Boundas.

5 Ladies and gentlemen, we'll take about a 10-minute
6 break.

7 *MR. STRAIN:* Ten minutes, your Honor.

8 *THE COURT:* Ten to fifteen. As soon as the jury will
9 get a drink and use the restroom, and then we will be back for
10 Abbott's closing argument.

11 *MR. STRAIN:* Thank you, your Honor.

12 *(Recess)*

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REPORTER'S CERTIFICATE

18 I, Molly N. Clayton, RPR, FCRR, Official Court Reporter
19 for the U.S. District Court, Southern District of Illinois, do
20 hereby certify that I reported with mechanical stenography the
21 proceedings contained in pages 3109 - 3172; and that the same
22 is a full, true, correct and complete transcript from the
23 record of proceedings in the above-entitled matter.

24 DATED this 21st day of March, 2015.

25

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Closing Argument, Plf

s/Molly Clayton, RPR, FCRR